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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/800,657	03/16/2004	Kazutami Sakamoto	250521US0CONT	1130
22850 7590 01/14/2008 OBLON, SPIVAK, MCCLELLAND MAIER & NEUSTADT, P.C. 1940 DUKE STREET ALEXANDRIA, VA 22314				
			EXAMINER WILLIAMS, LEONARD M	
			ART UNIT 1617	PAPER NUMBER
			NOTIFICATION DATE 01/14/2008	DELIVERY MODE ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

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Office Action Summary

Application No.

10/800,657

Applicant(s)

SAKAMOTO ET AL.

Examiner

Leonard M. Williams

Art Unit

1617

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 9-12, 14-20, 22, 23, 25-30, 41, 45 and 47-60 is/are pending in the application.
- 4a) Of the above claim(s) ____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☒ Claim(s) 9, 10-12, 14-20, 22-23, 25-30, 41, 45, and 47-60 is/are rejected.
- 7) ☐ Claim(s) ____ is/are objected to.
- 8) ☐ Claim(s) ____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on ____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. ____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- ☐ Notice of References Cited (PTO-892)
- ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- ☐ Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date ____.
- ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. ____.
- ☐ Notice of Informal Patent Application
- ☐ Other: ____.

Detailed Action

Response to Amendment/Arguments

Applicant's amendment received 10/18/2007 amending claims 9, 11, 14, 16, 20, 22, 25, 27, 41, 45, 47 and adding new claims 48-60 has been entered.

Applicant's arguments filed 10/18/2007 have been fully considered but they are not persuasive. Applicant's have amended claim 9 to exclude all compounds except pyrrolidonecarboxylic acid in the form of a salt with arginine and to limit the claim to improvement or promotion of blood circulation in skin. Further applicant's have added new claims 48-60, including a new method claim in claim 53 previously not presented.

The examiner respectfully points out that the 103(a) rejection of the last office action still reads on the claims as amended and on the new claims. This is amply shown on pages 3-5 of the last office action where it is shown that Baldacci et al. teach a method for restoring depressed immunodefenses via administration of L-arginine and its salt with L-2-pyrrolidone-5-carboxylic acid. Takayama further demonstrates that PCA can be used to increase the water solubility of allantoin and that PCA salts have strong moisturizing effect and also weak vasodilator properties. The examiner respectfully points out that vasodilation results in increased blood flow at the site and thus reads on the improvement or promotion of blood circulation in skin as presently claimed.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

Claims 9, 10-12, 14-20, 22-23, 25-30, 41, 45, and 47-60 are rejected under 35 U.S.C. 103(a) as being unpatentable over Baldacci (US Patent No. 4581371), in view of Takayama et al. (US Patent No. 4025525) and further in view of Noel (U.S. Patent No. 5141964).

Baldacci, in col. 1 lines 15-35 and claim 1, teach a method for restoring depressed immunodefenses comprising administering to a patient having depressed immunodefenses an immunomodulating composition comprising L-arginine, L-lysine, and their salts with L-2-pyrrolidone-5-carboxylic acid.

Baldacci, in col. 2 line 55 to col. 3 line 10, teach a pharmaceutical composition containing L-2-pyrrolidone-5-carboxylate of L-arginine (1 g, ~4% by weight), L-2-pyrrolidone-5-carboxylate of L-lysine (1g, ~4% by weight), potassium iodide, sodium

benzoate, fructose, ascorbic acid, sodium metabisulfite, lemon flavor, and deionized water.

Baldacci does not explicitly teach methods of treatment other than restoring depressed immunodefenses or cosmetic compositions in the form of a lotion, an emulsion, a gel, a cream, or an ointment.

Takayama et al. teaches, in col. 1 line 20 to col. 2 line 40, the use of 2-pyrrolidone-5-carboxylic acid (PCA) in order to increase the water solubility of allantoin and thus allantoin's moisturizing effect. Further Takayama et al discloses that PCA salts have a strong moisturizing effect and are therefore used in cosmetic formulations and that PCA salts also possess weak vasodilator properties.

Noel, in example 3, teaches a cosmetic composition comprising chitosan, gluconic acid, pyrrolidonecarboxylic acid (0.7% by weight), glucosamine HCl, arginine (0.6% by weight), and absorbed water.

Noel, in col. 2 lines 20-30, that the cosmetic compositions may be used to formulate creams, gels, milks, body emulsions, and liquid soaps.

It would have been obvious to one of ordinary skill in the art at the time the invention was made that the Baldacci compositions could be used in the formulations detailed in Takayama et al and Noel as Takayama et al. describes PCAs known use in cosmetic preparations as a moisturizer and Noel demonstrates the use of Balducci's compounds as evidenced by Noel example 3. One would have been motivated to use Balducci's compounds in Takayama et al. and Noel's formulations in order to increase the immunomodulating activities of Noel's cosmetic skin preparations and to take

advantage of the ability of PCA salts to increase aqueous solubility, moisturize, and increase vasodilation as disclosed by Takayama et al..

The examiner respectfully points out the following from MPEP § 2112.01: "[T]he discovery of a previously unappreciated property of a prior art composition, or of a scientific explanation for the prior art's functioning, does not render the old composition patentably new to the discoverer." *Atlas Powder Co. v. Ireco Inc.*, 190 F.3d 1342, 1347, 51 USPQ2d 1943, 1947 (Fed. Cir. 1999). Thus the claiming of a new use, new function or unknown property which is inherently present in the prior art does not necessarily make the claim patentable. *In re Best*, 562 F.2d 1252, 1254, 195 USPQ 430, 433 (CCPA 1977).

Conclusion

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of

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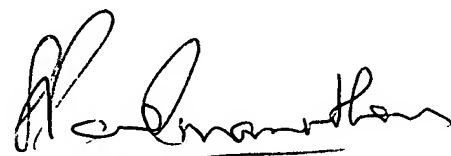
the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Leonard M. Williams whose telephone number is 571-272-0685. The examiner can normally be reached on MF 9-5:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Sreeni Padmanabhan can be reached on 571-272-0629. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

LMW



SREENI PADMANABHAN
SUPERVISORY PATENT EXAMINER